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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,346	03/01/2002	Allen Comer	STRATA-06949	3073

7590 05/05/2003
MEDLEN & CARROLL, LLP
Suite 350
101 Howard Street
San Francisco, CA 94105

EXAMINER

CHEN, SHIN LIN

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 05/05/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/087,346

Applicant(s)
Comer et al.

Examiner
Shin-Lin Chen

Art Unit
1632



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-54 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-6 and 8, drawn to a composition comprising a human skin equivalent, classified in class 424, subclass 424.
 - II. Claims 9 and 10, drawn to an isolated keratinocyte comprising DNA construct encoding GKLF, and an organotypic culture comprising said keratinocyte, classified in class 435, subclass 325.
 - III. Claims 11-16 and 18-22, drawn to a method of making skin equivalents having improved barrier function comprising providing keratinocytes and a culture comprising ascorbic acid and linoleic acid and culturing said keratinocyte, and the skin equivalent produced by said method, classifiable in classes 424 and 435, subclasses 424 and 373, respectively.
 - IV. Claims 7, 17 and 23-35, drawn to a method of making skin equivalents having improved barrier function comprising providing keratinocytes and a DNA construct expressing GKLF operably linked to an exogenous promoter, transfecting said keratinocytes with said DNA construct, and culturing said transfected keratinocyte, a human skin equivalent having keratinocytes expressing GKLF, and the skin equivalent produced by said method, classifiable in classes 424 and 435, subclasses 93.2, and 373 and 455, respectively.

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V. Claims 36-54, drawn to a method of screening compounds by using a skin equivalent, and a kit comprising said skin equivalent, classifiable in class 424 and 435, subclasses 9.81 and 810, respectively.

2. The inventions are distinct, each from the other because of the following reasons:

Groups I and II are distinct from each other because they are drawn to different compositions having different chemical structures, physical properties, and biological functions: a human skin equivalent vs an isolated keratinocyte. They has different uses and different classifications. The searches for groups I and II are not coextensive. Thus, groups I and II are patentably distinct from each other.

Groups I and III are distinct from each other because they are drawn to different compositions having different chemical structures, physical properties, and biological functions: a human skin equivalent vs a skin equivalent having improved barrier function. A skin equivalent having improved barrier function encompasses a human skin equivalent and other types of skin equivalent and it has improved barrier function. They have different classifications and the searches for groups I and III are not coextensive. Thus, groups I and III are patentably distinct from each other. Similarly, group I and V are distinct from each other for the same reasons.

Groups II and III are distinct from each other because they are drawn to different compositions having different chemical structures, physical properties, and biological functions: an isolated keratinocyte vs a skin equivalent. They has different uses and different

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classifications. The searches for groups II and III are not coextensive. Thus, groups II and III are patentably distinct from each other. Similarly, group II and V are distinct from each other for the same reasons.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MEP. § 806.05(h)). In the instant case the keratinocyte comprising DNA construct encoding GKLF can be used to produce recombinant GKLF protein.

Groups III and IV are distinct from each other because they are drawn to materially different methods using compositions that differ in chemical structures, physical properties, and biological functions: keratinocytes vs keratinocytes transfected with a DNA construct expressing GKLF. The methods differ at least in method steps, reagents and doses used, schedules used, response variables, and criteria of success. They have different classifications and require separate search. Thus, they are patentably distinct from each other.

Groups III-IV are distinct from group V because they are drawn to materially different methods that differ at least in objectives, method steps, reagents and doses used, schedules used, response variables, and criteria of success. They have different classifications and require separate search. Thus, they are patentably distinct from each other.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

